

used rubber gloves, swabs, gauze, tongue depressors, etc. Regulated medical waste classified in Risk Group 4 is nonmailable.

f. *Risk group* means a ranking of a microorganism's ability to cause injury through disease. A risk group is defined by criteria developed by the World Health Organization (WHO) that are based on the severity of the disease caused by the organism, the mode and

relative ease of transmission, the degree of risk to both an individual and a community, and the reversibility of the disease through the availability of known and effective preventive agents and treatment. There is no relationship between a risk group and a DOT packing group. Assignment to a risk group is based on the known medical condition and history of the source patient or animal, endemic local conditions,

symptoms of the source patient or animal, or professional judgment concerning individual circumstances of the source patient or animal. The sender is responsible for accurately ranking a mailable material within the correct risk group. Exhibit 8.2f details the criteria for each risk group according to the level of risk.

#### Exhibit 8.2f Risk Group Criteria

Risk group	Pathogen	Risk to individuals	Risk to community
4 .....	A pathogen that usually causes serious human or animal disease and that can be readily transmitted from one individual to another, directly or indirectly, and for which effective treatments and preventive measures are not usually available.	High .....	High.
3 .....	A pathogen that usually causes serious human or animal disease but does not ordinarily spread from one infected individual to another, and for which effective treatments and preventive measures are available.	High .....	Low.
2 .....	A pathogen that can cause human or animal disease but is unlikely to be a serious hazard, and, while capable of causing serious infection on exposure, for which there are effective treatments and preventive measures available and the risk of spread of infection is limited.	Moderate .....	Low.
1 .....	A microorganism that is unlikely to cause human or animal disease. A material containing only such microorganisms is not subject to regulation as a hazardous material, but it is subject to the packaging requirements in 8.10, unless otherwise noted in 8.0.	None or Very Low.	None or Very Low.

g. *Sharps*, for USPS purposes, means any object contaminated with a pathogen or that may become contaminated with a pathogen through handling or during transportation and that is also capable of cutting or penetrating skin or a packaging material. Sharps include used medical waste such as needles, syringes, scalpels, broken glass, culture slides, culture dishes, broken capillary tubes, broken rigid plastic, and exposed ends of dental wires. Sharps waste classified in Risk Group 4 is nonmailable.

h. *Toxin* means a Division 6.1 material from a plant, animal, or bacterial source. A toxin containing an infectious substance or a toxin contained in an infectious substance must be classed as Division 6.2, described as an infectious substance, and assigned to UN 2814 or UN 2900, as appropriate.

i. *Used health care product* means a medical, diagnostic, or research device or piece of equipment, or a personal care product used by consumers, medical professionals, or pharmaceutical providers that does not meet the definition of a diagnostic specimen, biological product, regulated medical waste, or sharps waste, is contaminated with potentially infectious body fluids or materials, and is not decontaminated or disinfected to remove or mitigate the infectious hazard

prior to transportation. A used health care product classified in Risk Group 4 is nonmailable.

#### 8.3 Nonregulated Materials

The following materials are not subject to regulation as Division 6.2 hazardous materials and are mailable when the packaging requirements in 8.10 are met:

a. A diagnostic (clinical) specimen known to contain or suspected of containing a microorganism in Risk Group 1, or that does not contain a pathogen. Also, a diagnostic specimen in which the pathogen has been neutralized or inactivated so that exposure to it cannot cause disease.

b. A biological product known to contain or suspected of containing a microorganism in Risk Group 1, or that does not contain a pathogen. Also any biological product, including an experimental product or component of a product, subject to Federal approval, permit, or licensing requirements, such as those required by the Food and Drug Administration (FDA) of the Department of Health and Human Services (HHS) or the U.S. Department of Agriculture (USDA).

c. Blood collected for blood transfusion or the preparation of blood products; blood products; tissues intended for use in surgical procedures; and human cell, tissues, and cellular and tissue-based products regulated

under authority of the Public Health Service Act and/or the Food, Drug, and Cosmetic Act. Also, blood collected for blood transfusion or the preparation of blood products and sent for testing as part of the collection process, except where the person collecting the blood has reason to believe it contains a pathogen in Risk Group 2 or 3, in which case the test sample must be packaged under 8.6.

d. A material, including a Division 6.2 waste, that previously contained an infectious substance that has been treated by steam sterilization, chemical disinfection, or other appropriate method, so it no longer meets the definition of an infectious substance in Risk Group 2, 3, or 4.

e. Forensic material in Risk Group 1 transported on behalf of a U.S. government, state, local, or Indian tribal government agency.

f. Environmental microbiological samples, such as samples of dust from a ventilation system or mold from a wallboard, collected to evaluate occupational and residential exposure risks.

#### 8.4 Packaging—General

All materials mailable under the provisions in 8.0 must be properly packaged. Exhibit 8.4a lists the specific reference in 8.0 under which each type of mailable material must be packaged.